

REMARKS

Claims 228-235, 244-271 and 274-281 are pending in this application. By this Amendment, claims 228, 233, 253, 265, 266, 276 and 278 are amended, claims 272 and 273 are canceled. Claims 228 and 233 are amended to include the subject matter of claims 272 and 273, respectively. Claim 253, 265 and 266 are amended for form. Support for the amendment to claims 276 and 278 can be found in Figures 11C and 18, and the corresponding description in the specification. No new matter is added.

Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

I. The Claims Define Patentable Subject Matter

The Office Action, in paragraph 5, rejects claims 228, 230-233, 235 and 272-275 under 35 U.S.C. §103(a) over EP 0 376 763 to McKelvey et al. (hereinafter "McKelvey"); in paragraph 6, rejects claims 229 and 234 under 35 U.S.C. §103(a) over McKelvey in view of WO 96/29865 to Fahy et al. (hereinafter "Fahy I"); in paragraph 7, rejects claims 244, 246-253, 255, 256, 258-263, 265 and 276-279 under 35 U.S.C. §103(a) over McKelvey in view of U.S. Patent No. 5,586,438 to Fahy (hereinafter "Fahy II") and U.S. Patent No. 6,238,908 to Armstrong (hereinafter "Armstrong"); in paragraph 8, rejects claims 245 and 257 under 35 U.S.C. §103(a) over McKelvey in view of Fahy II, Armstrong and Fahy I; in paragraph 9, rejects claims 254 and 271 under 35 U.S.C. §103(a) over McKelvey in view of Fahy II, Armstrong and U.S. Patent No. 5,451,524 to Coble et al. (hereinafter "Coble"); and in paragraph 10, rejects claims 264, 266-270, 280 and 281 under 35 U.S.C. §103(a) as being unpatentable over McKelvey in view of Fahy II, Armstrong and U.S. Patent No. 6,300,875 to Schafer. These rejections are respectfully traversed.

None of the applied references teaches or renders obvious a transporter that is adapted to receive the portable housing, the transporter being a portable organ perfusion apparatus, as

recited in independent claim 228; and placing the portable housing containing the organ in a transporter and transporting the organ in said portable housing in said transporter without removal of the organ from the portable housing, the transporter being a portable organ perfusion apparatus, as recited independent claim 233.

The Office Action, in paragraph 5, asserts that "the transportation unit [of McKelvey] suggested and discussed above would be a portable organ perfusion apparatus" based on the disclosure at col. 6, lines 1-19. However, McKelvey merely discloses at col. 6, lines 1-19, that "the removable unit 31 also allows the transfer of an organ contained therein from one transportation device to another (e.g., where the organ is transferred from a portable hand-carried device to a larger non-portable device at the organ destination)" (emphasis added). McKelvey does not teach that the portable hand-carried device is a portable organ perfusion apparatus.

A portable hand-carried device as disclosed in McKelvey does not suggest a portable organ perfusion apparatus. There is no disclosure in McKelvey regarding the structure of the portable hand-carried device.

Further, the Office Action's conclusory statement regarding the modification of McKelvey simply "in view of the disclosure" does not meet the articulated standard required to demonstrate obviousness. The Federal Circuit recently reaffirmed its prior holdings asserting that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006). See also the Supreme Court's reasoning in *KSR v. Teleflex*, requiring explicit "articulated reasoning with a rational underpinning" to support a legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350, slip op. at 14 (2007), citing *In re Khan* 441 F.3d 997, 998 (Fed. Cir. 2006). This standard is not met here as no articulated

reasoning with some rational underpinning is provided in order to meet the standard of obviousness required by the judicial precedent for modifying references in alleging obviousness. In other words, there is no rational basis for concluding that one of ordinary skill in the art would have understood that the portable hand carried device to be a portable organ perfusion apparatus. For example, based on McKelvey's disclosure, one of ordinary skill in the art would have understood that a portable hand-carried device was a cooler.

At least for the reasons discussed above, to conclude that, when confronted with the problem disclosed in the background portion of Applicants' disclosure, one might have turned to McKelvey to address that problem, is a conclusion that can only be arrived at through an improper application of hindsight reasoning based on the roadmap provided by Applicants' disclosure.

Fahy I, Fahy II, Armstrong, Coble and Schafer are not applied in a manner to overcome the above-identified shortfalls in the application of McKelvey to the subject matter of the pending claims.

For at least the foregoing reasons, the applied references cannot reasonably be considered to teach, or render obvious, the combinations of all of the features positively recited in independent claims 228 and 233. Additionally, claims 229-232, 234, 235, 244-271 and 274-281 are also neither taught, nor would they have been rendered obvious, by the applied references for at least the respective dependence of these claims, directly or indirectly, on an allowable base claim, as well as for the separately patentable subject matter that each of these claims recites.

Moreover, Applicants respectfully assert that none of the applied references teaches or would render obvious the transporter interfaced to a computer network, as recited in claims 280 and 281. The Office Action fails address these features in the rejection, and thus Applicants assert that this rejection is improper (see paragraph 10 of the Office Action).

The applied references also do not teach or render obvious the organ fitting configured (1) to at least one of adapt to or hold the organ independently and be removable from any of the organ perfusion apparatus, the transporter or the portable housing, and (2) to be received by the portable housing, as recited in claim 276, and as similarly recited in claim 278.

The Office Action acknowledges that McKelvey does not disclose this feature, but asserts that the pad 13 of Fahy II corresponds to the claimed organ fitting. However, the pad 13 is merely soft sterile foam material that supports weight of the organ and is analogous to pads used for shipment of objects, such as computers. Fahy II, col. 4, lines 7-62. Fahy II does not disclose that the pad 13 is removable. Thus, Applicants assert that Fahy II does not disclose the features of claims 276 and 278.

Accordingly, reconsideration and withdrawal of the rejections over any combination of the applied references are respectfully requested.

II. Double Patenting Rejection

The Office Action rejects claims 276-279 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 64 and 65 of U.S. Patent No. 6,673,594 (the '594 patent) in view of McKelvey. The rejection is respectfully traversed.

Applicants respectfully submit that the Examiner acknowledged during the prosecution of the '594 patent that the subject matter of claims 276-279 is patentably distinct from the claims of the '594 patent. In an Interview Summary for the '594 patent dated March 7, 2003, the Examiner asserted that he "would restrict claims 298-308 by original presentation." Independent claims 301 and 306 filed during the prosecution of the '594 patent were directed to a system for holding an organ for at least two of perfusion, storage and transport of the organ and a method of at least two of perfusion, storage and transport of an organ, respectively (See April 4, 2003 Amendment). Independent claims 228 and 233 include

the features recited in claims 301 and 306. Claims 276-279 depend from independent claims 228 and 233, which are directed to a system for holding an organ during perfusion, storage and transport of the organ and a method of perfusion, storage and transport of an organ, respectively. Thus, Applicants respectfully submit that the double patenting rejection of claims 276-279 is improper. See MPEP §804.

For at least these reasons, withdrawal of the double patenting rejection is thus respectfully requested.

III. Conclusion

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned representative at the telephone number set forth below.

Respectfully submitted,



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Attachment:

Petition for Extension of Time

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